

4187 FIRST AID KIT - 4187 first aid kit
Honeywell Safety Products USA, INC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

4187 First Aid Kit (FABC, ammonia inh, EW, Burn Jel, PVP wipes, alcohol wipes, sting relief, aypanal- 010552-3305)

First Aid Burn Cream

Active ingredient

Benzalkonium chloride 0.13%

Lidocaine HCl 0.5%

First Aid Burn Cream

Purpose

First aid antiseptic

External analgesic

First Aid Burn Cream

Uses

- prevent skin infection
- for temporary relief of pain associated with minor burns

First Aid Burn Cream

Warnings

For external use only

Do not use

- in or near the eyes
- if you are allergic to any of the ingredients
- in large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days

First Aid Burn Cream

Directions

- **adults and children 2 years of age and older:**

- clean the affected area
- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 2 years of age: consult a doctor

First Aid Burn Cream

Other information

- tamper evident sealed packets
- do not use if packet is opened or torn

First Aid Burn Cream

Inactive ingredients

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

First Aid Burn Cream

Questions

1-800-430-5490

Sting Relief

Active ingredient

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief

Purpose

Antiseptic

Topical pain relief

Sting Relief

Uses

- prevent infection in minor scrapes, and temporary relief of itching of insect bites

Sting Relief

Warnings

For external use only

Flammable, keep away from open fire or flame

Do not use

- over large areas of the body
- in eyes
- over raw or blistered areas

Stop use and ask a doctor

- if conditions worsen or persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Sting Relief**Directions**

- **adults and children 2 years and older:** Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

Sting Relief**Inactive ingredients**

benzalkonium chloride, menthol, and purified water

Sting relief**Questions or Comments**

1-800-430-5490

4187

010552-3305 Kit Contents

1 KNUCKLE BAND 8 PER
1 FIRST AID BURN CREAM 6 PER
1 AMMONIA INHALANTS 10 PER
1 EYE DRESS PKT W/4 ADH STRIPS
1 GAUZE COMPRESS, 1728 SQ IN 1
1 INSTANT COLD PACK 4" X 6"
1 BUFFERED EYE WASH 1 OZ BTL
1 ADHESIVE BDG, PLSTIC, 1" X 3" 16 PER
1 BURN JEL 1/8 OZ, 6 PER
2 ALCOHOL PREP PADS 10P
1 PVP IODINE WIPES 10 PER
LBL STOCK 6-3/8" X 4"
LBL STOCK 4" X 2-7/8"
1 LBL STOCK 3" X 1-7/8"
1 KIT STL 16 UN (VERTICAL)
1 LABL INSTR FA REV A
1 STING Relief WIPES 10
1 AYPANAL NON-ASP 25/2

Eyesaline***Active ingredient***

Sterile Water 99%

Eyesaline***Purpose***

Eyewash

Eyesaline***Uses***

- for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

Eyesaline***Warnings*****For external use only-**

Obtain immediate medical treatment for all open wounds in or near eyes.

To avoid contamination, do not touch tip of container to any surface.

Do not reuse. Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

Stop use and ask a doctor if

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Eyesaline***Directions***

- remove contacts before using
- twist top to remove
- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

Eyesaline***Inactive ingredients***

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyes aline**Questions**

1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI 02917

Ammonia Inhalent**Active ingredient**

Ammonia 15%

Ammonia Inhalent**Purpose**

Respiratory stimulant

Ammonia Inhalent**Uses**

- to prevent or treat fainting

Ammonia Inhalent**Warnings****For external use only****Do not use**

- if you have breathing problems such as asthma or emphysema

Stop use and ask a doctor if

- condition persists

Keep out of reach of children

If swallowed get medical help or contact a Poison Control Center right away.

Ammonia Inhalent**Directions**

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapor

Ammonia Inhalent**Other information**

- store at room temperature away from light

Ammonia Inhalent**Other information**

- store at room temperature away from light

Ammonia Inhalent**Inactive ingredients**

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

Ammonia Inhalent**Questions or Comments**

1-800-430-5490

Burn Jel**Active ingredient**

Lidocaine HCl 2.0%

Burn Jel**Purpose**

External analgesic

Burn Jel**Uses**

- temporarily relieves pain due to minor burns

Burn Jel**Warnings****For external use only****Do not use**

- on large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

Burn Jel**Directions**

- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Burn Jel**Other information**

- store at room temperature

- do not use if opened or torn

Burn Jel

Inactive ingredients

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water ...

Burn Jel

Questions

1-800-430-5490

Povidone Iodine Swab

Active ingredient

Povidone-iodine solution USP, 10% (equivalent to 1% titratable iodine)

Povidone Iodine Swab

Purpose

First aid antiseptic

Povidone Iodine Swab

Uses

- first aid to help prevent the risk of infection in minor cuts, scrapes, and burns

Povidone Iodine Swab

Warnings

For external use only

Do not use

- over large areas of the body
- on individuals who are allergic or sensitive to iodine

Ask a doctor before use if you have

- deep or puncture wounds,
- animal bites
- serious burns

When using this product

- do not use longer than one week unless directed by a doctor

Stop use and ask a doctor if

- conditions persists or gets worse
- irritation and redness develops

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Povidone Iodine Swab

Directions

Reverse cardboard sleeve, then crush at dot between thumb and forefinger. Allow solution to saturate tip and apply solution to injury.

- clean affected area
- apply to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard swab after single use

Povidone Iodine Swab

Other information

- store at room temperature away from light
- keep from freezing or excessive heat
- do not use if package is torn or open

Povidone Iodine Swab

Inactive ingredients

citric acid, disodium phosphate, nonoxynol-9, sodium hydroxide, water

Povidone Iodine Swab

Questions and comments

1-800-430-5490

Alcohol Wipe

Active ingredient

Isopropyl alcohol 70%

Alcohol Wipe

Purpose

First aid antiseptic

Alcohol Wipe

Uses

- first aid to help prevent infection in minor cuts, scrapes, and burns

Alcohol Wipe

Warnings

For external use only

Do not use

- in the eyes
- over large areas of the body

Ask a doctor before use if you have

- deep or puncture wounds
- animal bites
- serious burn

When using this product

- do not use longer than one week unless directed by a doctor

Stop use and consult a doctor

- if condition persists or gets worse

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

Alcohol Wipe***Directions***

- clean the affected area
- apply wipe to affected area 1 to 3 times daily
- may be covered with a sterile bandage
- discard wipe after single use

Alcohol Wipe***Other information***

store at room temperature 15⁰ to 25⁰ C (59⁰ to 77⁰F)

Alcohol Wipe***Inactive ingredient***

water

Alcohol Wipe***Questions***

1-800-430-5490

Aypanal***Active ingredient***

Acetaminophen 325 mg

Aypanal***Purpose***

Pain reliever/ fever reducer

Aypanaly***Uses***

- temporarily relieves minor aches and pains due to the common cold and headache - temporarily

reduces fever

Keep out of reach of children.

Keep out of reach of children.

Aypanal

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product:

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- If a skin rash occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease

Ask a doctor or pharmacist before use if

- you are taking the blood thinning drug warfarin

Stop using and ask a doctor if

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Overdose warning

- In case of accidental overdose, get medical help or contact a Poison Control Center right away.
- Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal

Directions

do not take more than directed (see overdose warning)

▯adults and children 12 years of age or older

- take two tablets every 4-6 hours while symptoms last
- do not take more than 12 tablets in 24 hours

children 6 to under 12 years of age

- take 1 tablet every 4-6 hours while symptoms last
- do not take more than 5 tablets in 24 hours

children under 6 years consult a doctor

Aypanal

Other information

- store at room temperature 15⁰ to 30⁰ C (59⁰ - 86⁰ F)
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Aypanal

Inactive ingredients

corn starch, microcrystalline cellulose, povidone, sodium starch glycolate, stearic acid

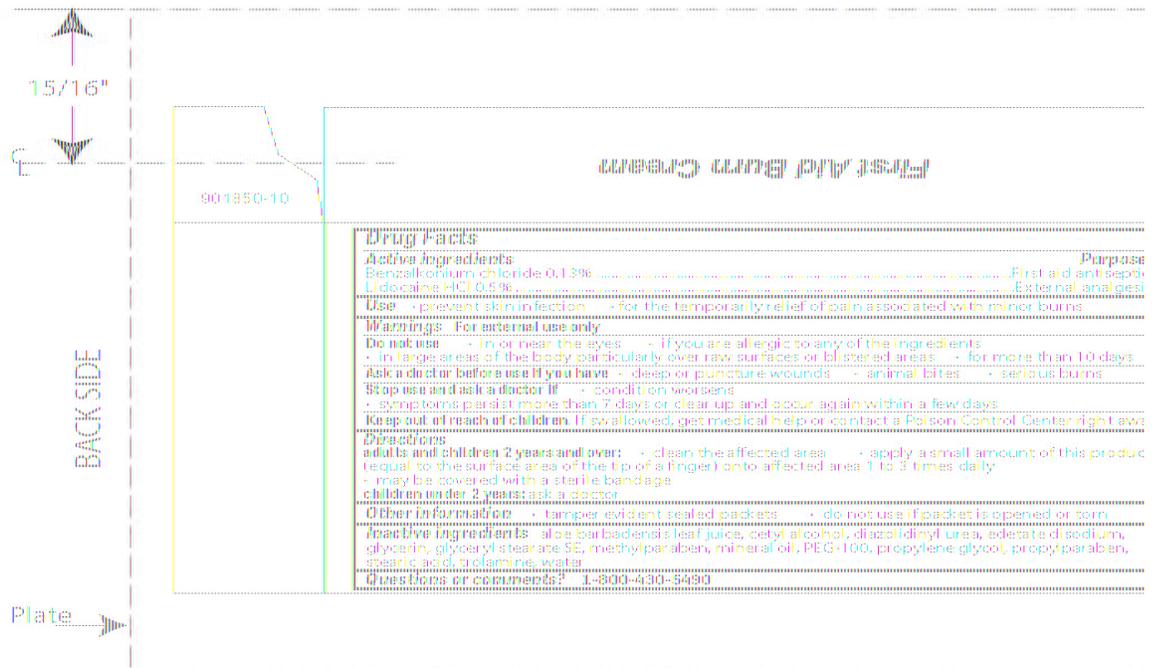
Aypanal

Questions

1-800-430-5490

First Aid Burn Cream

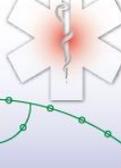
Principal Display Panel



Principal Display Panel

825366 Rev B



<p>Honeywell 032043P</p>  <p>Sting Relief Wipes</p> <p>Use for: Minor Cuts • Scrapes • Insect Bites</p> <p>Single Use Pouches Saturated Wipes</p> <p style="text-align: right;">100 wipes</p>	<p>Honeywell 032043P</p>  <p>Sting Relief Wipes</p> <p>Use for: Minor Cuts • Scrapes • Insect Bites</p> <p>Single Use Pouches Saturated Wipes</p> <p style="text-align: right;">100 wipes</p>	<p>Drug Facts</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Active Ingredients</th> <th style="text-align: left;">Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl alcohol 50.0%</td> <td>First aid antiseptic</td> </tr> <tr> <td>Lidocaine HCl 2.0%</td> <td>Topical analgesic</td> </tr> </tbody> </table> <p>Uses First aid to help prevent infection in minor scrapes and temporary relief of itching of insect bites.</p> <p>Warnings For external use only. Flammable, keep away from fire or flame.</p> <p>Do not use • over large areas of the body • in eyes • over raw or blistered areas</p> <p>Stop use and ask a doctor • if conditions worsen or persist for more than 7 days or clear up and occur again within a few days.</p> <p>Keep out of reach of children. If swallowed get medical help or contact Poison Control center right away.</p> <p>Directions • adults and children 2 years and older: apply to cleaned affected area not more than 3 times daily. • children under 2 years of age: consult a doctor.</p> <p>Inactive Ingredients benzalkonium chloride, menthol, purified water</p> <p>Questions or comments? 1-800-430-5490</p>	Active Ingredients	Purpose	Ethyl alcohol 50.0%	First aid antiseptic	Lidocaine HCl 2.0%	Topical analgesic	<p>Distributed by Honeywell Safety Products, USA, Inc. Smithfield, RI 02917</p> <p>www.honeywellsafety.com</p> <p>USA 1-800-430-5490 0-401-943-4460</p>  <p>2 1812 10 1284 1</p> <p>Made in USA Packaged in Mexico</p>
Active Ingredients	Purpose								
Ethyl alcohol 50.0%	First aid antiseptic								
Lidocaine HCl 2.0%	Topical analgesic								

4187 Kit Label
010552-3305

FIRST AID KIT



KANSAS CITY SOUTHERN RAILWAY

Eyesaline Principal Display Panel



eyesaline®

**LAVAOJOS
EYESALINE**

Solución
Isotónico Estéril

**EYESALINE
EYEWASH**

Sterile
Isotonic Solution

**LAVAGE
OCULAIRE
EYESALINE**

La Solution
Isotonique Stérile

16 fl. oz. (473 mL)

TAMPER-EVIDENT CAP.
TAPA CON SELLO DE SEGURIDAD.
BOUCHON INDICATEUR D'INFRACTION.

NPN: 80057528



3 64809 45033 7

Drug Facts (for USA only)

Active ingredient	Purpose
Sterile water 99%	Eyewash

Uses
for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.

Warnings
For external use only - Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away

Stop use and consult a doctor if:

- you experience eye pain
- you experience changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- remove contacts before using
- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

Inactive ingredients
sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Questions? Call 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

space for lot code and supplier part number

PEEL / PELAR / PELER

Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo	Propósito
Agua estéril 99%	Lavaojos

Usos
para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aéreos, o agua de cloruro

Advertencias
Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte.

No se use

- si la solución se enturbia o cambia de color
- si tiene heridas abiertas en o cerca del ojo, obtenga ayuda médica de inmediato

Deje de usar y consulte a un médico si:

- experimenta dolor de ojo
- cambio de visión
- rojez continuo o irritación del ojo
- la condición empeora o persiste

Manténgase fuera del alcance de los niños.
En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.

Instrucciones

- quítese los lentes de contacto antes de usar la solución
- tuerza la tapa para quitar
- enjuague el área afectada según se necesite
- controle el chorro haciendo presión en la botella
- si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia

Ingredientes inactivos
cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico

¿Preguntas? Llame al 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Information

Usages
Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.

Advertissements
Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jetez-les.

Ne pas utiliser

- si la solution a changé de couleur ou si elle est brouillée
- si vous avez des plaies ouvertes aux yeux ou à proximité, consultez immédiatement un médecin

Cesser d'utiliser la solution et consulter un médecin

- vous ressentez une douleur oculaire
- si votre vision change
- rougeur ou irritation persistante des yeux
- condition empire ou persiste

Garder hors de la portée des enfants.
En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.

Mode d'emploi

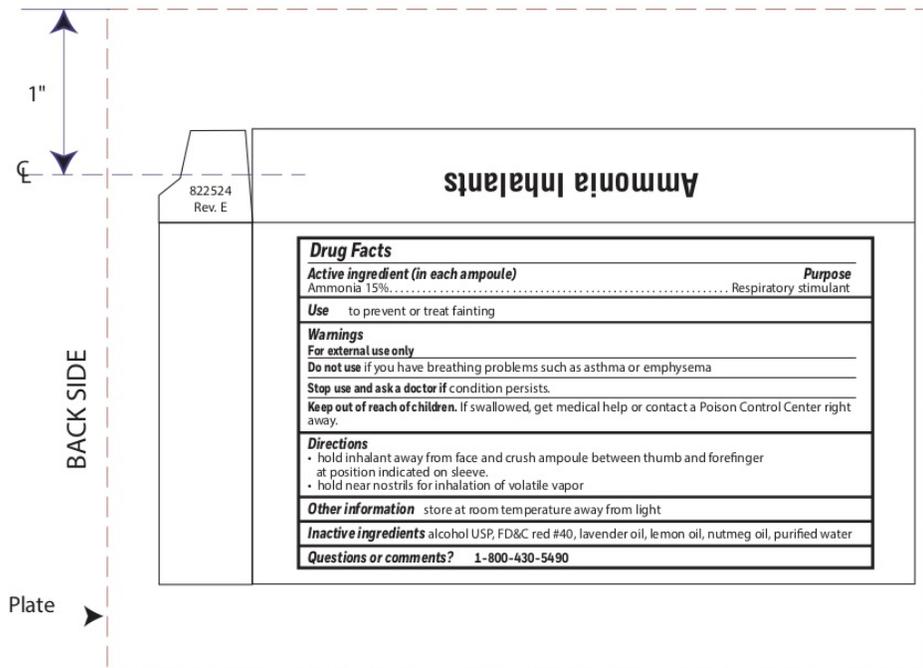
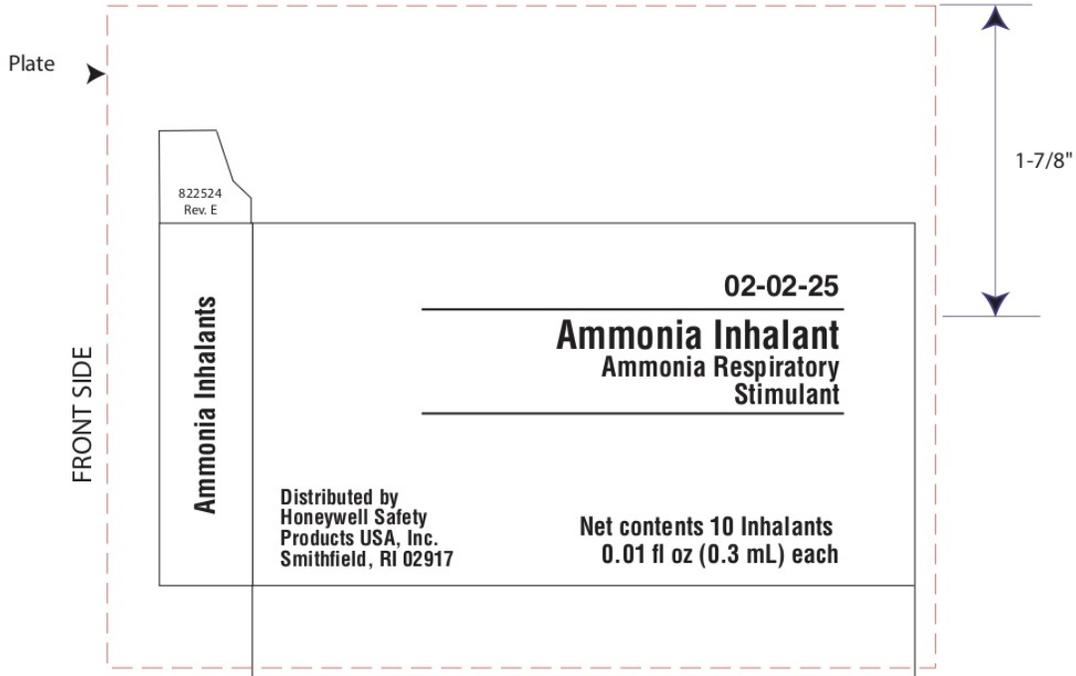
- enlever les verres de contact avant l'utilisation
- dévisser le bouchon pour l'enlever
- rincer la zone touchée selon les besoins
- ajuster le débit d'écoulement de la solution en augmentant ou en réduisant la pression exercée sur le contenant
- si nécessaire, continuer de rincer avec une solution de rinçage oculaire d'urgence ou une douche

Ingédients
eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium

Des questions? Faites le 1-800-430-5490
Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

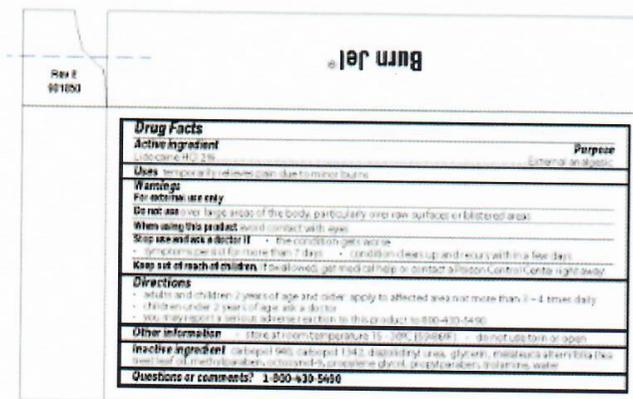
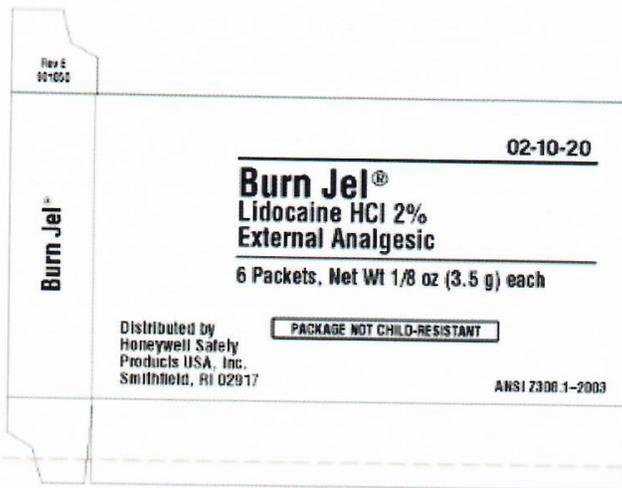
Ammonia inhalent Principal Display Panel

796006 Rev. E Unit Carton Printing Plate for "A" size carton.

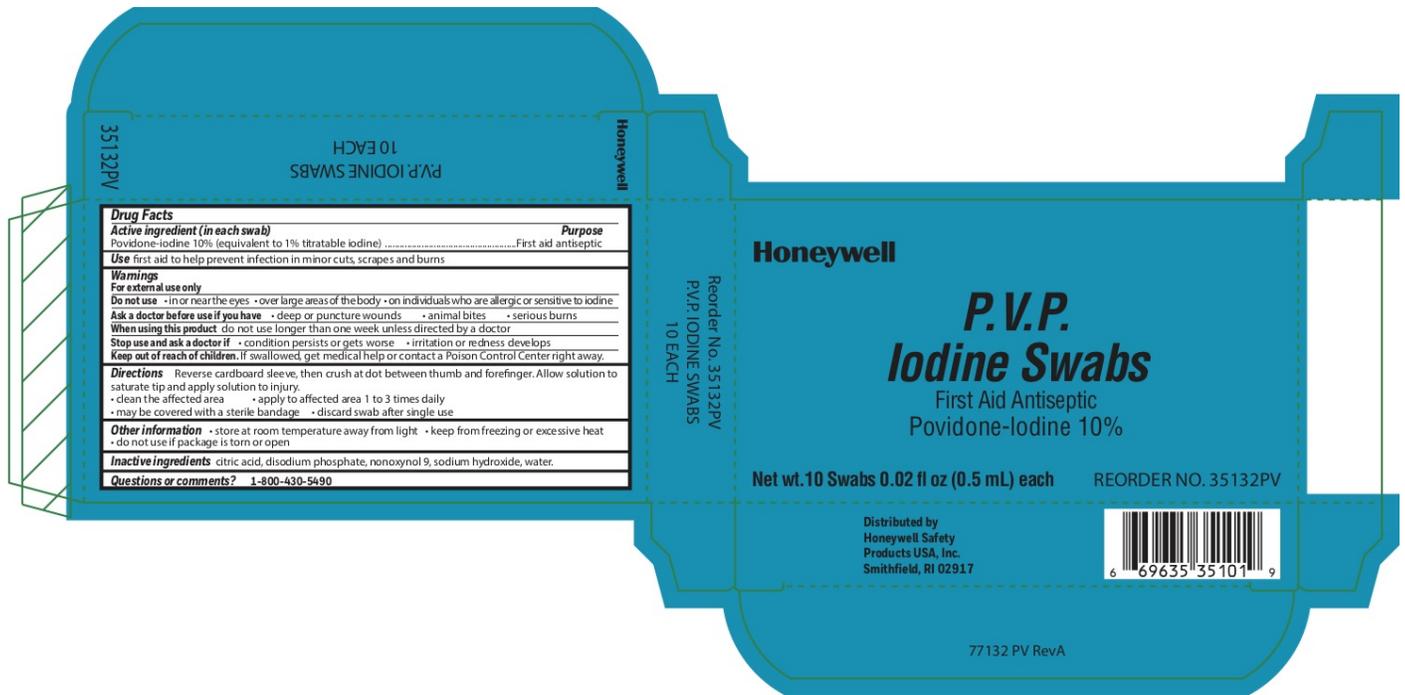


796006 Rev. E (page 3 of 3)

Principal Display Panel

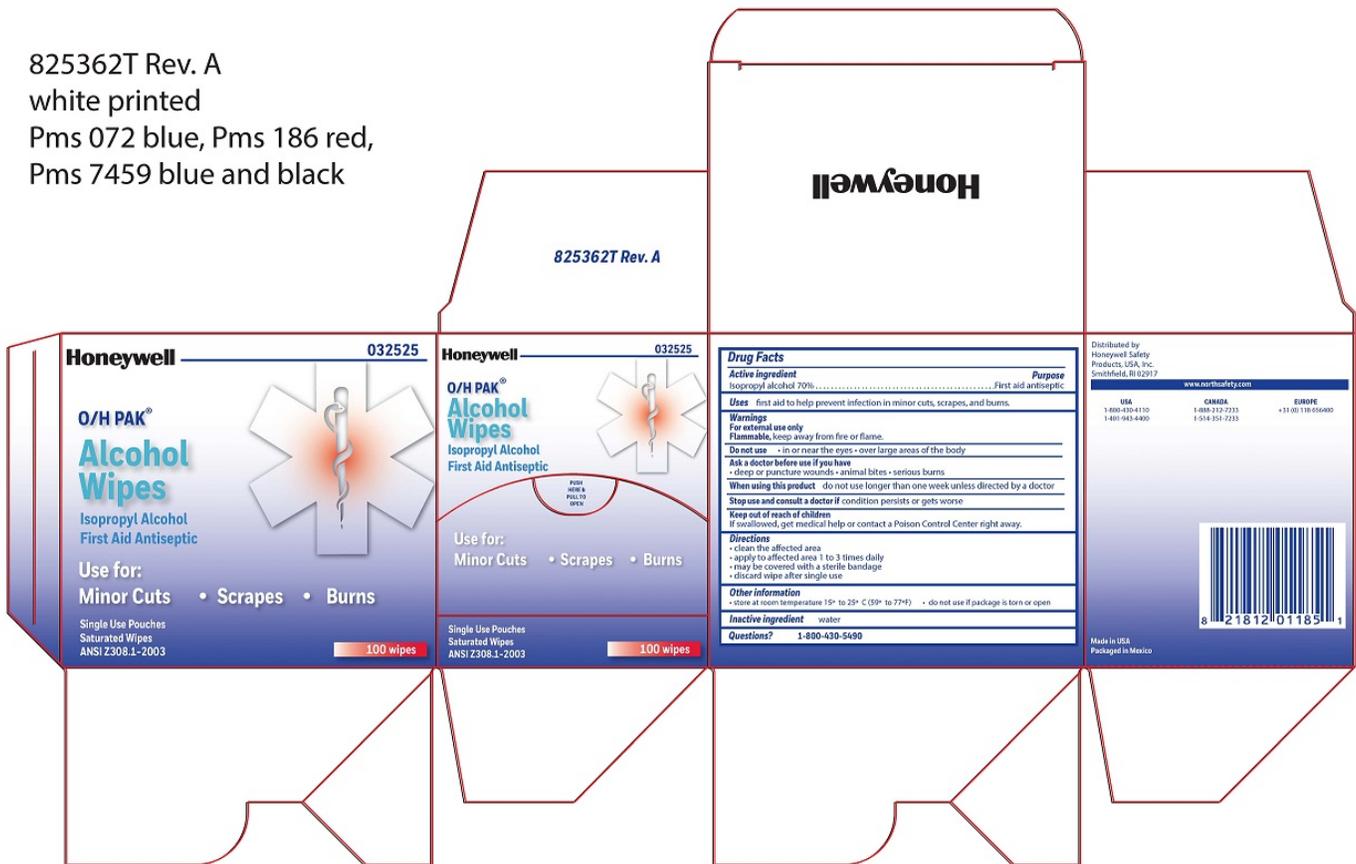


Povidone Iodine Swab
Principal Display Panel



Alcohol Wipe
Principal Display Panel

825362T Rev. A
 white printed
 Pms 072 blue, Pms 186 red,
 Pms 7459 blue and black



Aypanal

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information

Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2017	

Part 2 of 8

FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information

Item Code (Source)	NDC:0498-0903
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0903-34	10 in 1 BOTTLE, UNIT-DOSE		
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	12/20/2017	

Part 3 of 8**EYESALINE EMERGENCY EYEWASH**

purified water liquid

Product Information

Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	12/18/2018	

Part 4 of 8**AMMONIA INHALENT**

ammonia inhalent inhalant

Product Information

Item Code (Source)	NDC:0498-3334
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)	AMMONIA	0.045 g in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1 NDC:0498-3334-00 0.3 mL in 1 AMPULE; Type 0: Not a Combination Product

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 5 of 8

ALCOHOL WIPE

isopropyl alcohol swab

Product Information

Item Code (Source)	NDC:0498-0143
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0143-04	0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2018	

Part 6 of 8

PVP IODINE WIPE

povidone-iodine 10% swab

Product Information**Item Code (Source)** NDC:0498-0121**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
NONOXYNOL-9 (UNII: 48Q180SH9T)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0121-00	0.3 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 7 of 8**BURN JEL**

gel for burns gel

Product Information**Item Code (Source)** NDC:0498-0203**Route of Administration** TOPICAL**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
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TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER HOMO POLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
CARBOMER HOMO POLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
TEA TREE OIL (UNII: VIF565UC2G)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part348	09/19/2018	

Part 8 of 8

AYPANAL NON-ASPIRIN

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2001
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	circle;U
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/10/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - Honeywell Safety Products USA, INC (079287321)**Establishment**

Name	Address	ID/FEI	Business Operations
James Alexander		040756421	manufacture(0498-3334)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4187)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-2001)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0903, 0498-0203)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0143)

Establishment

Name	Address	ID/FEI	Business Operations
Sion Biotext Medical		532775194	manufacture(0498-0121)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America Inc		874965262	manufacture(0498-0733)

Revised: 3/2019

Honeywell Safety Products USA, INC